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| 10/699,088 | 10/30/2003 | Dana Ault-Riche | 17102-005001 / 25885-1754 | 7850 |
| 20985 | 7590 | 09/19/2005 | EXAMINER | |
| FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081 | | | WESSENDORF, TERESA D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1639 | |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,088

Applicant(s)

AULT-RICHE ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final *for restriction only*
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-134 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-134 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claim(s) 1, 5-7, 9-17, 20-24 and 123 drawn to a method of distributing tag molecules and collection of tagged molecules.

Group II, claim(s) 2-4, 8, 18-19, 25-40, 121, 122, 124-132, drawn to a method of distributing nucleic acid molecules among members of a starting library.

Group III, claim(s) 42-54, drawn to a capture system of tagged polypeptides (or antibodies).

Group IV, claim(s) 41, 55-68 and 133-134, drawn to a collection of tag molecules.

Group V, claim(s) 69-116, drawn to a method for capturing molecules.

Group VI, claim(s) 117-118, drawn to a method of identifying modulators.

Group VII, claim(s) 119-120, drawn to a method of sorting molecules or reducing diversity.

The inventions are distinct each from the other because of the following reasons:

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The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods using different components and steps that produces different results/ compounds with different effects and/or functions. For example, Group I uses other compounds besides nucleic acid. The process of Group VI drawn to identifying modulators contain different process steps from the method of Group VII of sorting molecules for reduced diversity.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different compounds that have different functions/effects. For example, the capture system of Group III which relates e.g., to biological molecule is different from the collection of tag molecules such as the

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fluorescent moieties for which the capture system may or may not contain. See further the different species encompassed by these different compounds, below.

Inventions (III and IV) and (I, II, V, VI and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different statutory subject matter i.e., different methods and structurally different compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-VII, specifically the literature searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A). Starting Library as recited in e.g., claim 25 or claim 41.
 - 1. Nucleic acid (e.g., cDNA)
 - 2. Polypeptide (if elected a species is required e.g., antibody or a specific fragment of the antibody)

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B). Additional agents as recited in claim 51.

C). Tagged molecules as recited in e.g., claims 73-77.

1. Nucleic acid
2. Peptides
3. Antibodies or fragments
4. Library of molecules

D). Capture agents as recited in claim 81.

1. Receptors as recited in claim 100 (Note a species is required. The lists below are more of a genus and classed only as species to differentiate one from the other. If there is a sequence, preferably a specific sequence.)

- a. Cell surface receptors
- b. T-cell
- c. MHC peptides
- d. MHC peptide complexes
- e. B cell
- f. ICAMS
- g. Toll-like
- h. PPAR ligands
- i. Ion channels
- j. Chemokine
- k. Nicotine acetylcholine
- l. Dopamine
- m. Muscarinic
- n. Small molecule
- o. TNF
- p. IL
- q. BCAMS
- r. INF

2. Ligands
3. Drugs
4. Enzymes
- 5 Modified enzymes

E). Solid support as recited in claim 85 (the species are in claim 90).

1. Silicon
2. Celluloses
3. Metal
4. Polymeric surfaces
5. Radiation grafted supports

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F). Tagging of capture agents by linking to: (as recited in claim 87)

1. Electronic
2. Chemical
3. Optical
4. Color-coded labels

G). Biological particles (cells) as recited in claim 97.

1. Immune cells
2. Neurons
3. Cancer cells
4. Bacterial
5. Infected cells

H). Staining (detection means) as recited in claims 113 (114).

1. Fluorescent dyes
2. Immunostain
3. Semiconductor
4. Enzyme labels
5. Luminescent labels

Each of the species covered in each of the genus e.g., subgroup A differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 41, 42, 69, 117, 119 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**


Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

September 14, 2005